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April 24, 2000

MEMORANDUM

SUBJECT: *DICLOFOP-METHYL* - Report of the FQPA Safety Factor Committee

FROM: Brenda Tarplee, Executive Secretary
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Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
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PC Code: 110902

The FQPA Safety Factor Committee met on April 10, 2000 to evaluate the hazard and exposure data for diclofop-methyl and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be removed (1x) in assessing the risk posed by this chemical.

I. HAZARD ASSESSMENT

(Correspondence: C. Jarvis to B. Tarplee dated March 30, 2000)

A. Adequacy of the Toxicology Database

The toxicology database for diclofop-methyl is complete for FQPA assessment. The following studies are available and considered acceptable: developmental toxicity studies in rats and rabbits; 2-generation reproduction study in rats. In addition, based on the available data, the HIARC concluded that a developmental neurotoxicity study in rats is not required.

B. Determination of Susceptibility

The HIARC concluded that data provided no indication of increased susceptibility of rats or rabbits following *in utero* exposure to diclofop-methyl or of rats following pre-/postnatal exposure. In the prenatal developmental toxicity study in rabbits, no evidence of developmental toxicity was seen even in the presence of maternal toxicity at the highest dose tested. And in the prenatal developmental toxicity study and the two-generation reproduction study in rats, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of maternal/parental toxicity.

II. EXPOSURE ASSESSMENTS

A. Dietary (Food) Exposure Considerations

(Correspondence: C. Jarvis to B. Tarplee dated March 30, 2000)

Diclofop-methyl is registered as a herbicide for use on wheat and barley. Tolerances are established for the combined residues of diclofop-methyl and its metabolites, 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoic acid and 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy]propanoic acid, in or on barley and wheat commodities at 0.1ppm (40 CFR §180.385). There no established Codex maximum residue limits for diclofop-methyl in/on plant or animal commodities.

On April 4, 2000, the HED Metabolism Assessment Review Committee determined the residue of concern for plant commodities is diclofop-methyl and its metabolites, 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoic acid and 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy] propanoic acid. For animal commodities, the residue of concern is diclofop-methyl and its metabolite, 2-[4-(2,4-dichlorophenoxy)phenoxy] propanoic acid.

Sources of monitoring data available for diclofop-methyl include 1994-1998 FDA surveillance data which report non-detectable residues in barley and wheat (LOD is 0.015 ppm); and 1995-1997 USDA Pesticide Data Program data which indicate detectable

residues in two samples of wheat out of a total of 1563 samples (LOD is 0.006 ppm). Residue data are also available from field trial studies. In addition, a quantitative usage analysis (QUA) has been provided by the Biological and Economic Analysis Branch (BEAD) which includes the weighted average percent crop treated as well as the estimated maximum %CT .

The HED Dietary Exposure Evaluation Model (DEEM) is used to assess the risk from acute and chronic dietary exposure to residues in food resulting from the use of diclofop-methyl. These analyses will be very refined (Tier 3) using the available monitoring data to calculate anticipated residues as well as the appropriate %CT information which results in a more realistic estimate of the dietary (food) exposure resulting from the use of diclofop-methyl. The 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy]propanoic acid compound (included in the tolerance expression) was not detected in either laboratory or field studies.

B. Dietary (Drinking Water) Exposure Considerations

(Correspondence: S. Dutta to B. Grim and J. Holmes dated April 3, 2000)

The environmental fate database for diclofop-methyl is adequate for preliminary drinking water assessment. These data indicate that because the parent compound hydrolyzes rapidly to diclofop acid after incorporation and because the degradate is mobile to moderately mobile in soil, runoff to surface water of the degradate may follow a rainfall/irrigation event. However, the amounts in runoff are expected to be low. Considering the current maximum annual application rate of 1 lb. a.i./acre, the probability of contamination of ground waters by diclofop-methyl residues is considered to be very low.

Sources of ground and surface water monitoring data include:

A recent prospective groundwater study (PGW) completed by the Registrant in Wadena County, Minnesota on vulnerable (sandy) soil during which time recharge of the aquifer was confirmed/conditions were favorable for leaching. Study results up to 2 years after the initial application of diclofop-methyl at 1 lb. active ingredient/acre (the maximum label rate for a broadcast application) show that diclofop methyl residues (either parent or the acid degradate) were not detected in ground water (LOD = 1 ppb).

In a Canadian study conducted 1985-1987 in a small agricultural watershed, observed levels of diclofop methyl ranged from 0.05 to 0.47 ppb in surface water (pond) samples. There were 37 detections out of 105 samples in ground water, ranging from 0.17 to 1.61 ppb, with one report of a maximum of 4.88 ppb. Application rate(s) and timing of application(s) were not reported.

Limited STORET data are available. There were no detections (LOD = 0.1 ppb) in 20 ground water samples and 52 stream samples taken in Minnesota in 1992. All reported values for 11 ground water samples and 13 canal samples taken in Idaho in 1990-1991 were < 0.1 ppb. A single stream sample from Colorado in 1989 reported a value of 0.05 ppb. No information was provided on whether samples were taken from areas where diclofop methyl was used.

Estimated Environmental Concentrations for drinking water risk assessments were calculated using the PRZM/EXAMS model for the surface water and the SCI-GROW model for ground water. It is noted that the EECs reported in the Drinking Water memo were calculated before the implementation of the EFED policy on Index Reservoir and Percent Crop Area. It is likely that the EECs recalculated using the Index Reservoir and Percent Crop Area guidance will not differ substantially from those already provided.

C. Non-Occupational (Residential) Exposure Considerations

(Correspondence: C. Jarvis to B. Tarplee dated March 30, 2000)

Diclofop-methyl is currently registered for use on golf course turf which could result in post-application exposure to infants and children entering treated areas.

No chemical-specific data are available to assess residential exposure to diclofop-methyl therefore, the DRAFT Standard Operating Procedures (SOPs) for Residential Exposure Assessments were used. The DRAFT SOPs normally rely on one or more upper-percentile assumptions and are intended to represent Tier 1 assessments. Assessments resulting from the use of these SOPs are likely to be an over-estimation of the level of exposure.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

A. Recommendation of the Factor

The Committee recommended that the FQPA safety factor be **removed (1x)**.

B. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed for diclofop-methyl because:

1. The toxicology database is complete for the assessment of the effects following *in utero* and/or postnatal exposure to diclofop-methyl;
2. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to diclofop-methyl in the available toxicity data;
3. The HIARC determined that a developmental neurotoxicity study is not required for diclofop-methyl;
4. The dietary (food and drinking water) and non-dietary exposure assessments will not underestimate the potential exposures for infants and children from the use of diclofop-methyl.